

## PATENT COOPERATION TREATY

## PCT

REC'D 25 JAN 2005

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

WIPO PCT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference<br>PC-21005724   | FOR FURTHER ACTION See Form PCT/IPEA/416                 |  |
| International application No.<br>PCT/SE2003/001412   | International filing date (day/month/year)<br>11.09.2003 | Priority date (day/month/year)<br>12.09.2002 |
| International Patent Classification (IPC) or national classification and IPC<br>C12N 13/00, C12N 15/87 // C12M 1/42, A61N 2/02 |  |  |
| Applicant<br>Genovis AB et al  |  |  |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
 

|                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

|   |   |
|---|---|
| Date of submission of the demand<br>24.03.2004  | Date of completion of this report<br>29.12.2004                         |
| Name and mailing address of the IPEA/SE<br>Patent- och registreringsverket<br>Box 5056<br>S-102 42 STOCKHOLM<br>Facsimile No. +46 8 667 72 88<br>Form PCT/IPEA/409 (cover sheet) (January 2004) | Authorized officer<br>Micael Oswald/EÖ<br>Telephone No. +46 8 782 25 00 |

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2003/001412

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))  
☐ publication of the international application (under Rule 12.4)  
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

☒ the international application as originally filed/furnished

☐ the description:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the claims:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the drawings:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2003/001412

## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 10-11 (partly)

because:

- ☒ the said international application, or the said claims Nos. 10-11 (partly) relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv): Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for said claims Nos. \_\_\_\_\_

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

- |                            |                          |                                   |
|----------------------------|--------------------------|-----------------------------------|
| the written form           | <input type="checkbox"/> | has not been furnished            |
|                            | <input type="checkbox"/> | does not comply with the standard |
| the computer readable form | <input type="checkbox"/> | has not been furnished            |
|                            | <input type="checkbox"/> | does not comply with the standard |

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/SE2003/001412

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

|                               |        |             |     |
|-------------------------------|--------|-------------|-----|
| Novelty (N)                   | Claims | <u>1-11</u> | YES |
|                               | Claims |             | NO  |
| Inventive step (IS)           | Claims | <u>1-11</u> | YES |
|                               | Claims |             | NO  |
| Industrial applicability (IA) | Claims | <u>1-11</u> | YES |
|                               | Claims |             | NO  |

## 2. Citations and explanations (Rule 70.7)

The present application relates to a particle (a transportation particle), which can be used to transport substances through biological membranes. The particle contains a magnetically susceptible material and a difunctional molecule, which contain a binding site for a substance to be transported and a binding site for the biological membrane.

The following documents (D) are cited in this report:

1. (D1) WO 0118168 A1.
2. (D2) WO 9528494 A1.

D1 (see specially page 8, lines 10-23 and fig. 4) discloses a particle, which can be used to transport substances through biological membranes. The particle contains a magnetically susceptible material and the whole particle is a difunctional particle, which contain a binding site for a substance to be transported and a binding site for the biological membrane.

D1 is regarded as being the closest prior art to the subject-matter of claims 1-11. The subject-matter of claims 1-11 differs from D1 in that the difunctional molecule of the claimed invention is a separate fusion protein or fusion molecule where the binding site and the recognition site are located very close to each other. This is in contrast to D1 where the binding and recognition molecules are randomly distributed on the particle.

D2 (see abstract) describes a difunctional molecule (a gene delivery fusion protein), which contains a binding site (nucleic acid binding domain) for a substance to be transported and a binding site (targeting component) for a biological membrane. This gene delivery fusion protein can also contain a membrane-disrupting component. The subject-matter of claims 1-11 differs from D2 in that the membrane transport is facilitated by a magnetically inducible component not by a part of a protein as in D2.

.../...

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

The cited document represents the general state of the art. The invention defined in claims 1-11 is not disclosed by these documents.

The cited prior art does not give any indication that would lead a person skilled in the art to the claimed invention. Therefore, the claimed invention is not obvious to a person skilled in the art.

Accordingly, the invention defined in claims 1-11 is novel and is considered to involve an inventive step. The invention is industrially applicable.